RECONSTRUCTION OF TEMPOROMANDIBULAR JOINT USING DISTRACTION OSTEOGENESIS

A Dissertation Submitted to the
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In partial fulfillment of the requirement for the degree of

MASTER OF DENTAL SURGERY
BRANCH – III
(ORAL & MAXILLOFACIAL SURGERY)

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CERTIFICATE

This is to certify that **Dr. PUNEET KUMAR GUPTA** Post Graduate Student (2007-2010) in the Department of Oral and Maxillofacial Surgery, Tamilnadu Government Dental College & Hospital, Chennai has done this dissertation titled **"RECONSTRUCTION OF TEMPOROMANDIBULAR JOINT USING DISTRACTION OSTEOGENESIS"** under my direct guidance and supervision in partial fulfillment of the regulations laid down by the Tamilnadu Dr.M.G.R. Medical University, Chennai for M.D.S., Branch–III Oral and Maxillofacial Surgery, Degree Examination.

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I dedicate this study to my parents and brothers.

Last but not the least I would like to seek the blessings of the Almighty without whose grace this endeavour wouldn't have been possible

DECLARATION

I, **Dr. PUNEET KUMAR GUPTA** , do hereby declare that the dissertation titled **"RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT USING DISTRACTION OSTEOGENESIS "** was done in the Department of Oral and Maxillo Facial Surgery, Tamil Nadu Government Dental College & Hospital, Chennai 600 003. I have utilized the facilities provided in the Government dental college for the study in partial fulfillment of the requirements for the degree of **Master of Dental Surgery** in the speciality of Oral and Maxillo Facial Surgery **(Branch III)** during the course period **2007-2010** under the conceptualization and guidance of my dissertation guide**, Prof. Dr. G.UMA MAHESWARI, MDS.**

I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from the Tamil Nadu Government Dental College & Hospital.

I also declare that no part of this work will be published either in the print or electronic media except with those who have been actively involved in this dissertation work and I firmly affirm that the right to preserve or publish this work rests solely with the prior permission of the Principal, Tamil Nadu Government Dental College & Hospital, Chennai 600 003, but with the vested right that I shall be cited as the author(s).

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Signature of Head of the department *Signature of the Head of the Institution*

LIST OF ABBREVIATIONS

TMJ	-	Temporo Mandibular Joint
R	-	Right
L	-	Left
Pre op	-	Pre Operative
Post op	-	Post Operative
OPG	-	Ortho Pantomogram
Lat. Ceph	-	Lateral Cephalogram
DO	-	Distraction Osteogenesis

CONTENTS

INTRODUCTION

INTRODUCTION

Temporomandibular joint is one of the most complex of all synovial joints. It plays an important role in establishing and maintaining proper form & function within the stomatognathic system.

It acts as a growth centre for the mandible in the prepuberty stage of growth & is also essential for the functions of mastication , speech , airway support and deglutition both in childhood & adulthood.

There are certain abnormal conditions like traumatic irreparable condylar injuries, idiopathic condylar resorption, TMJ ankylosis, congenital anomalies, severe degenerative diseases & benign or malignant tumours involving the condyle which require surgical removal of the affected condyle which may affect the form and function, so reconstruction of TMJ is required to restore the same .

Goal of TMJ reconstruction includes restoration of the height of the mandibular ramus , normalization of the occlusion & TMJ function , freedom from pain, normal mouth opening & long term stability .

The complex nature of the joint anatomy & its related masticatory muscles makes reconstruction of TMJ a formidable & challenging task.

Numerous surgical procedures have been advocated for the same like autogenous bone graft and alloplastic materials.

In some of the procedures where autogenous bone grafts were used , it was associated with the problem of overgrowth or resorption of graft leading to unstable occlusion or ankylosis of joint with added donar site morbidity.

Use of the alloplastic materials were associated with problems of mechanical wear, failure of uptake, forging body reaction & breakdown of the articular surfaces.

Recently, Transport Distraction Osteogenesis[4,66] has been applied for the reconstruction of TMJ to prevent the difficulties encountered in using autogenous and alloplastic grafts.

The principle used in Transport DO is a classic Illiazarov technique[25] as in reconstruction of large osseous defects.

Costantino et al were the first to attempt Bifocal distraction in the canine mandible & reconstructed a segmental defect with Transport distraction.

In transport DO, a small segment of bone called the transport disc is slowly moved away from the host bone , into a defect. Osteogenesis occurs at the trailing edge of the transport disc (connecting it with the host bone), while a cap of fibrocartilage forms at the disc's leading edge. This latter phenomenon, which can cause difficulty in closing a large segmental defect, can be used to

advantage in reconstruction of the TMJ. A transport disc is fashioned from the ramus or angle of the mandible and is slowly moved into the glenoid fossa.Regenerate bone at the trailing edge of the disc forms a new ramus or condylar neck, while fibrocartilage at the leading edge becomes an articular surface.

AIM OF THE STUDY

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The aim of this clinical study was to evaluate the use of transport distraction osteogenesis in the reconstruction of Ramus-Condyle unit of the Temporomanddibular joint by using an indigeniously designed internal distraction device.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

STUDIES ON NON- VASCULARISED AUTOGENOUS BONE GRAFT AS MODE OF TREATMENT USED FOR THE RECONSTRUCTION OF TMJ

Lanfrancht (1955) [58]

reported the first successful autogenous transplant of the 2nd metatarsal joint to TMJ after condylectomy,

Dingman R.O (1964)[11]

used autogenous 5th metatarsal transplant for mandible condyle reconstruction. He reported satisfactory function & good range of action.

Rowe N.L (1972)[59]

Stated that the condyle which is the functional growth centre when destroyed produced deformity of the face which can be corrected by CCG.

Kennnet S. (1973)[35]

Recommended CCG over metatarsal graft because it not only restores the height but also initiate secondary graft.

Ellis Ed.III, Carlson (1986)[13]

They had conducted a study to compare the histomorphologic feature of costochondral joint & sternoclavicular joint to that of TMJ.

They showed that TMJ & Sternoclavicular joint are very similar morphologically throughout the growth period However, Costochondral joint didnot resemble the condyle but appeared to more similar to growth plate of long bone epiphysis. They indicated that Sternoclavicular joint may be more suitable for mandibular condylar replacement than Costochondral joint.

Kumoona (1986)[37]

He used chondro-osseous iliac crest graft for the stage reconstruction of ankylosed TMJ in children.

He showed that the graft has to react to functional stimuli, this enables it grow in multi-directional manner.

Lindquist C., Rhinkari A.,Tasaner et al (1986)[39]

In their clinical study of 60 patients who underwent costochondral arthroplasties for nearly half of the cases , Ankylosis was main indication for operation. The results showed that In 67% of patients ,post operative function of the mandible was considered good to excellent .

Polilis C, Eric F , Bossuyl M(1986)[56]

They used CCG for the replacement of the condyle following TMJ ankylosis release. Long term followup evaluation showed very satisfactory cosmetic & functional results.

They suggested that in children this graft allows harmonious growth of the mandible due to characterstic of costochondral cartilage.

Poswillo D.E(1986)[57]

He considered that CCG is the most suitable method for reconstruction of mandibular condyle. Creeping substitution of osteoid does not comprise the osteochondral graft.

The study emphasized the importance of transferring only a thin cartilage cap on an osteochondral graft for optimal survive of cartilage cells.

Obeid G, Guttenberg SA, Console PW (1988)[53]

They also used costochondral graft in condylar replacement and mandibular reconstruction in 22 patients (2-11yrs), they concluded that both functional and esthetics result were good to excellent and indicated that free costochondral graft is a successful and physiological second stage surgical option for reconstruction of hypoplastic portion of mandible in children.

Nelson C.L (1989)[52]

He had concluded that biologic replacement of diseased / deformed mandibular condyle in the adult is preferable to alloplastic reconstruction. The replaced tissues also adapts to the functional demands even in the adults. The author had used CCG as biologic replacement of TMJ.

Kaban L.B , Perrott D.H , Fisher K (1990)[32]

They formulated a management protocol for TMJ patients which consisting of 1) aggressive resection 2) Ipsilateral coronoidectomy 3) contrallateral coronoidectomy when necessary 4) lining of the TMJ with temporal fascia / cartilage 5) reconstruction of ramus with a CCG 6) rigid fixation 7) early mobilization & aggressive physiotherapy.

The protocol was evaluated retrospectively in 14 patients with a follow up of 1 year, facial asymmetries present in all unilateral cases remained corrected & mean mouth opening post operatively (36% increases) was recorded.

Stricken , Chassagne (1990)[65]

They advised the use of head of the second metatarsal bone as a microanastomatic transfer of condyle reconstruction especially in children.

Guyuron B, Lasa CI Jr(1992)[22]

They reported the long term follow up of 8 adolescent patients who underwent reconstruction of the TMJ & ramus for TMJ ankylosis with costochondral grafts and based on their study and review of the literature they concluded that, Growth pattern of costochondral graft is extremely unpredictable. Reankylosis is common problem following costochondral graft reconstruction. Mandible overgrowth on grafted side can actually be more

troublesome. They recommend that this procedure be performed only on severe deficiencies of mandible.

Hening T.B , Ellis Ed. , Carloson D.S (1992)[23]

They designed the study to investigate the long term effects of transplanted clavicle to TMJ in juvenile monkey.

They showed that continued & potentially harmonious growth of the mandible occurs following transplantation of the sternal end of the clavicle & they concluded that sternal end of the clavicle may be viable option in mandibular condylar transplant surgery.

Welford L.M , Coltrell D.A , Henry C (1995)[72]

They evaluated the long term outcome of 52 sternoclavicular grafts for TMJ reconstructions in 38 patients.

They supported the use of sternoclavicular graft for TMJ reconstructions in selected patients & demonstrated a high failure rate in patients with previous proplast / Teflon implants.

Dodsan T.B , Bay R , Pfeffle R.C (1997)[12]

They evaluated the efficacy of cranial bone graft in reconstruction of the mandibular condyle.

They concluded that full thickness cranial bone graft provided a functional joint , resisted resorption. So, cranial bone graft may therefore provide a suitable alternative to other autologus / alloplastic graft material for reconstruction of human mandibular condlye in non growing patient.

Gunaseelan R (1997)[20]

He reconstructed the condyle using the excised ankylosed mass in 3 patients. This technique has given good results & alternative to other methods of reconstruction in adults.

KO EW, Huang CS, Chen YR (1999)[36]

They used Costochondral graft (CCG) in children for temporomandibular joint reconstruction and concluded that using CCG to reconstruct TMJ ankylosis in children provide a functional condyle with growth potential. However there is a possibility of excessive growth of the graft, resulting in deviation of chin and mandibular prognathism.

Long H.Y , Xiaommy G (2002)[40]

They described the use of autogenous coronoid graft for lengthening the ramus in patients with lonf standing TMJ ankylosis & severe mandibular retrognathia.

They concluded that children suffering from TMJ ankylosis , coronoid process can be used for mandibular lengthening.

Patrick C , Crawford M.H , Hollies L.H (2008)[59]

They tried composite costochondral Illiac crest bone graft to reconstruct TMJ for improving the structural stability.

Zhu S , Hu Jing , Liang X (2008)[73]

They described the condylar reconstruction by free grafting of autogenous coronoid process in 15 patients with TMJ ankylosis.

They concluded that autogenous coronoid process could be considered as option for reconstruction of mandibular condyle in growing individuals.

STUDIES ON VARIOUS OSTEOTOMIES AS MODE OF TREATMENT USED FOR RECONSTRUCTION OF TMJ

Stadnicki G (1971)[64]

He reported an unusal incidence of a double condyle in the TMJ . An osseous unilateral ankylosis occurred after trauma caused by forceps at birth. It was surgically treated by osteotomy of the mandibular ramus. 2 cork were wedged between posterior teeth for 21 days to prevent the contraction of scar around new pseudojoint . A 6 year observation was found to be satisfsactory.

Markowitz R, Allen P, Duffy M.T (1989)[42]

They described ramus osteotomies as an alternative technique for reconstruction of TMJ & performed this technique on 4 patients.

They concluded that these osteotomies have better functional results.

STUDIES ON VARIOUS VASCULARISED AUTOGENOUS BONE GRAFT AS MODE OF TREATMENT USED FOR RECONSTRUCTION OF TMJ

Dattilo D.J , Granick M, Soteranous G (1986)[10]

They illustrasted the use of free vascularised whole joint transfer from the second toe to replace the TMJ & ramus of the mandible.

Graft provided adequate range of motion & stable reconstruction of the ramus.

Wax, Mark K,Hanson , Juliane (2000) [70]

They did retrospective analysis in 17 patients who underwent fibula free flap reconstruction of TMJ.

They concluded that primary reconstruction of TMJ with microvascular fibula flap is a viable & effective means of restoring function . the majority of patients are able to resume oral feeds , obtain excellent cosmetic results & maintain intelligible speech.

Guyot L , Richard O , Layoun W (2002)[21]

They studied 11 patients who underwent condylar reconstruction with free fibular transplant.

They found rounding off of the end of the graft & also there was no evidence of ankiylosis due to presence of intact TMJ disc.

Bond S.E , Saeed N.R , Cussons P.D (2004) [6]

They reconstructed the TMJ by transfer of fre vascularised second metatarsal in 9 patients & they advocated this technique for autogenous salvage reconstruction in joints that have been previously operated on unsuccessfully.

Gracia R.G , Gias L.N , Chancon J.L (2008)[16]

They described their experience in treatment of 6 patients who underwent mandibular resection including condyle .All of them underwent condylar reconstruction by free fibular flap.

They concluded that fibula flap directly fitted into the glenoid fossa , constitute a reliable method in condyle reconstruction. However possibility of severe complication such as ankylosis has to be considered.

STUDIES ON VARIOUS ALLOPLASTIC MATERIALS AS MODE OF TREATMENT USED FOR RECONSTRUCTION OF TMJ

Tauras , Jordon (1976) [67]

They reported a case of TMJ ankylosis resulting from trauma & infection . The treatment consisted of arthroplasty using cast gold prosthesis over the mandibular stump. Gold was selected because of its strength, malleability & tissue tolerance.

John N, Kent et al (1986)[39]

They used glenoid fossa prosthesis alone in combination with metallic condyle in 192 joints. The overall success rate was 91.5%. The disadvantage was the lack of options if prosthesis fails.

Philip W, Boyne J (1990)[55]

They reported a case of 8 year old girl with TMJ ankylosis. The Delrine condyle fixed in titanium mesh were installed, after mandible was positioned to a reasonable occlusion. Jaw exercises were advocated. The mouth opening was 30 mm in a 2 year follow up.

Walford, Cottrell (1994)[71]

They conducted a study of 56 patients with 100 reconstructed TMJ using Techmedica custom made total joint system.

It indicated that joint prosthesis seems to provide favourable results in reconstructing multiple operated joint & those with previously placed alloplastic implants.

Mercuri L.G, Wolford L, Sandus B (1995)[45]

They performed TMJ reconstruction on 215 patient who had TMJ problems or undergoing for previous TMJ surgeries using CAD/CAM TMJ reconstruction systems.

They concluded that custom CAD/CAM TMJ reconstruction systems seems to be useful in the treatment of multiple operated and / or anatomically mutilated TMJ.

Saeed N.R, Hensher R, Mcleod M.H (2002)[61]

They described retrospective study on TMJ reconstructions involving 49 patients treated with costochondral graft & alloplastic joints.

They concluded that more re-operations were required in autogenous groups. They recommended alloplastic reconstruction in patient with history of ankylosis, multiple operation & after previous alloplastic joints.

STUDIES ON DISTRACTION OSTEOGENESIS TECHNIQUE AS MODE OF TREATMENT USED FOR RECONSTRUCTION OF TMJ

Ilizarov (1957)[25]

Introduced distraction osteogenesis, gave unique protocols for distraction & discussed over theoretical and clinical aspects on regeneration of tissues using distraction osteogenesis for limb lengthening.

Synder C, Levine G.A, Swanson H.M et al (1973)

They gave first report of experimental distraction of the craniofacial skeleton. They created a cross bite by removing 1.5 cm segment of canine mandible. They distracted the mandible back to its original length by using modified external fixator device.

Mc carthy , Schrieber , Karp (1992)[43]

They performed first human clinical trial for distraction osteogenesis to correct mandibular hypoplasia secondary to hemifacial microsomia and TMJ ankylosis with successful and predicted results.

Meyer V, Meyer T (1994) [46]

They performed a study on 36 rabbits to evaluate the effect of magnitude & frequency of interfragmentary strain on the tissue response to DO.

They concluded that the magnitude & not the frequency of mechanical loading control the differentiation of bone cells & subsequent formation of bone tissues.

Mc Cormick SK, Mc Carthy JG, Grayson BH (1995)[44]

They suggested that the condyle on affected side resemble that of contralateral unaffected side following distraction in cases of hemifacial microsomia. Also there was no deformational changes observed on the unaffected condyle.

Moshief R et al (1996)[50]

They did an experimental study in sheep to show the vascular supply to the new distracted bone.

Fisher E, Staffenberg D.A, Mc carthy (1997)[14]

They studied the effect of distraction on the associated muscle of mastication. Biopsy of muscle showed that muscle affected by distraction in the same plane & vector adapts with compensatory regeneration & hypertrophy , while those in a different plane showed the evidence of atrophy with decreased protein synthesis.

Corcoran J. Et al (1997)[9]

They presented the experience of DO of the neomandible constructed from CCG.

Hikiyi H, Takali T (2000)[24]

They studied the applicability of the transport DO with an internal appliance for the reconstruction of TMJ in 97 white rabbits.

They observed that new bone & large amount of condyle were absorbed microscopically in distraction gap. A collagenous like structure & cap over the leading edge of transport segment. This case may be substitute for an articular disc. The bone remodelled resembled condyle. They concluded the bone transport technique a presuming for TMJ reconstructions.

Gateno J, Teichgraeber J, Aquilous E (2000)[15]

They developed a method for planning of 3- dimensional remodelling & animation to stimulate DO in virtuality.

Franciso , Castano J, Troulis M.J et al (2001)[8]

They studied the proliferation of masseter myocytes following distraction in porcine mandible. The results showed proliferation of the masseter myocytes following distraction.

Ruhaini K.A (2001) [1]

He showed the effect of applying resorbable calcium sulphate material to newly distraction bone for hastening osteogenesis during consolidation period.

Ruhaini K.A (2001)[2]

He distracted bone in mandible at different interval & different daily rates of distraction with goal of attaining an universally accepted distraction protocol . Rate of distraction was 0.5mm twice/day,1mm/day, 1mm twice daily & 2mm once daily. Results showed 1.0 mm once daily produced ideal osteogenesis.

Bueno R.P, Villa E, Careno A (2001)[7]

They gave an algorithem table for the diagnosis & treatment planning for DO. They concluded distraction as a definite treatment in case with isolated mandibular hypoplasia.If additional maxillary deformity is present, mandibular distraction must be performed first followed by maxillary correction later.

Meyer et al (2001)[47]

They investigated the contributors of various cytokines that involved in mechanically related bone formation when strain are applied during mandibular elongation.

Thurmulla P, Troullis M (2002)[68]

The purpose of this study was to test the feasibility of a ultrasound to evaluate in an experiment mandibular DO wound.

The results of the study indicate that ultrasound is potential useful for assessment of bone formation in DO wound.

Tuz H, Kisnicki K.S et al (2003)[69]

They evaluated short term structural changes in masseter muscles of rabbit after DO. They showed that structure of masseter muscle is influenced during & shortly after mandibular DO. Atrophic changes of the ipsilateral masseter muscle may be regarded as regenerative response that occur during & shortly after DO.

Kisnicki R.S (2004)[34]

In his study, he assessed the outcome of a protocol incorporating DO for condyle reconstruction. He reconstructed the condyle/ Ramal unit after excision of ankylosed mass in 10 patients. He concluded that this technique obviated the immobilization period & allowed early physiotherapy. An additional advantage would be when comply with post operative protocol condylar reconstruction & remodelling was gained without any predictable consequences.Restoration of forces acting upon the neocondyle/ ramal unit also had a positive effect on facial growth.

Jhu S, Jing Hu, Ying B (2006)[29]

They investigated the histomorphologic changes in the newly formed condyle reconstructed by transport DO through a non human

primate model. They concluded that neocondyle with functional shape can be created by transport DO & suggested this technique as an alternative technique for the reconstruction of condyles.

Kyun UK,Kyo chung et al (2006)[38]

They compared modified DO protocol with conventional DO protocol on healing bone formation. Computer simulation was performed to understand the mechanical environment of modified DO protocol, which applies compression during the consolidation period.

They concluded that modified DO protocol of adding compression during the early consolidation period of conventional DO protocol. This new technique appears to provide faster and denser bone regeneration.

Shetyne P.R, Graipen BH, Machool RJ et al (2006)[63]

They evaluated long term mandibular skeletal stability & growth following unilateral mandibular distraction in growing children.

Tuzuner A.M (2006)[3]

They evaluated the response of mandibular ramus following vertical lengthening by means of DO. They included 8 patients & vertical height of mandible reconstructed by transportation of bone segment using DO.

They concluded that Acute one stage of vertical lengthening of mandibular ramus reveals somewhat unstable response thereby complicating a favorable outcome. In this clinical study initial gain that was achieved by DO for ramus lengthening was maintained in 6month follow-up period.

Schwartz HC, Relle RJ (2008)[66]

They evaluated the use of transport DO in reconstruction of the ramus–condyle unit (RCU) of the TMJ.

They concluded that transport DO is a promising treatment option for TMJ reconstruction. It shares all of the advantages of autogenous bone grafting without the disadvantages of a donor site.

Kaban L.B, Bouchard C et al (2009)[31]

They gave 7 steps protocol for the management of TMJ ankylosis in children The protocol consists of 1)aggressive excision of the fibrous and/or bony ankylotic mass, 2) coronoidectomy on the affected side, 3) coronoidectomy on the contralateral side, if steps 1 and 2 do not result in a maximal incisal opening greater than 35 mm or to the point of dislocation of the unaffected TMJ, 4) lining of the TMJ with a temporalis myofascial flap or the native disc, if it can be salvaged, 5) reconstruction of the ramus condyle unit with either distraction osteogenesis or costochondral graft and rigid fixation,

and6) early mobilization of the jaw. If distraction osteogenesis is used to reconstruct the ramus condyle unit, mobilization begins the day of the operation. In patients who undergo costochondral graft reconstruction, mobilization begins after 10 days of maxillomandibular fixation. Finally (step 7), all patients receive aggressive physiotherapy.

MATERIALS & METHODS

MATERIALS AND METHODS

The clinical study on "*Reconstruction of the Ramus –Condyle unit of the Temporomandibular Joint using Transport Distraction"* was done in the department of oral & maxillofacial surgery, Tamil Nadu Government Dental College & Hospital, Chennai.

The criteria for selection of patients included,

1. Ankylosis cases, irreparable condylar fractures, severe degerative joint diseases, tumor resection & congenital anomalies of any age groups & sex.
2. Patients who were motivated enough to comply with the distraction regimen.

Four patients were selected, three male and one female with ages ranging from (9-36 year). 3 patients were having unilateral TMJ ankylosis and 1 patient was having condylar hyperplasia. Of the Ankylosis cases(3 in numbers) for 2 patients simulataneous interpositional arthroplasty using temporalis myofascial flap followed by ramus – condyle unit reconstructed using unilateral internal distraction device done.For the other 2 patients who were treated earlier , only ramus – condyle unit were reconstructed using unilateral internal distraction device.

Evaluation of the patient included a thorough and detailed history, clinical examination, facial photographs and radiographic examination.

HISTORY:

Included chief complaints, history of present illness, previous surgical and medical history.

CLINICAL EXAMINATION:

Included

- Examination of the mandibular deformity.
- Amount of mouth opening
- Deviation of the chin.
- Occlusion of teeth.
- Pain in joint region.
- Other associated deformities.

RADIOGRAPHIC EXAMINATION:

Included

- Orthopantogram (OPG)
- 3D CT scan
- Frontal cephalogram(Grummon's analysis)
- Lateral cephalogram

ASSESSMENT OF VERTICAL RAMAL HEIGHT OF MANDIBLE

Measurement of vertical height of ramus was done both on the affected and unaffected side, and the deficiency on the affected side was recorded using OPG, 3D CT scan, lateral and frontal cephalograms.

OPG was used to determine vertical ramus height on both side by following method.

Affected side:

Tangential line was drawn on the side of ramus connecting the following points:-

- Most prominent point on the curvature of antegonial notch.
- Cut end following gap arthroplasty & condylectomy of the superior border of ramus.

Unaffected side:

Tangential line was drawn on the sides of ramus connecting the following points:-

- Most prominent point on the curvature of antegonial notch.
- Superior most part of the condyle.

Thereby the distance between these two above marked points gives height of the ramus on both the sides.

Vertical ramus deficiency on both side was also confirmed by,

- 3D CT scan

- Frontal cephalogram (using grummon's analysis).

ASSESSMENT OF OSTEOTOMY CUT AND VECTOR PLACEMENT

- Osteotomy cut was planned using OPG as a guide.
- L shaped osteotomy cut is designed on remaining posterior ramus & angle.
- Vertical osteotomy cut was planned approximately 12- 15 mm from posterior border of ramus of the mandible from sigmoid notch region & it was parallel to a vector that bring the disk into glenoid fossa.
- Horizontal osteotomy cut was planned parallel to inferior border of mandible.

ASSESSMENT OF LINGULA

Lingula distance was measured from superior end of the affected ramus & also from posterior border of ramus in order to avoid injury to neurovascular bundlesusing OPG & 3D-CT scan.

AMOUNT OF DISTRACTION

Amount of distraction required was determind by measuring amount of deficiency in length of ramus of the mandible, by comparing the lengths of ramus of mandible on both affected & Unaffected sides.

ARMAMENTARIUM:

The armamentarium required for this study apart from the routine surgical instruments were,

1) Distraction device.
2) Distraction kit.

Distraction device:

An indigenously designed unilateral internal distractor made of stainless steel was used.

It had 2 attachment plates & ome activation rod.

A. Superior attachment plates

It was triangular in shape, of 8× 10 mm in size, having holes (3 in numbers) of 1.5 mm size. It had socket for activation rod.

B. Inferior attachment plates

It was L shaped, of 10×10 mm in size, having 1.5mm diameter holes (3 in numbers) & also had socket for activation rod.

C. Activation rod

It was cylindrical in shape & threaded . Length of the rod varies from 60-90 mm depending on the patients.One turn of screw for activation given us 0.5 mm of movement.

Distraction device selected can be used for approx. 30 mm of lengthening.

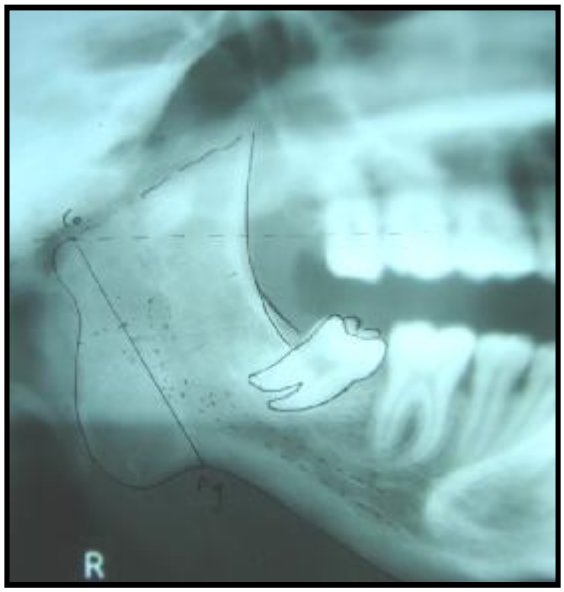
Distraction kit:

It consist of,

- Templates: A acrylic template was made for guiding the placement of the osteotomy cut.
- 701 Bur was used for corticotomy & 1.1mm drill bits was used for hole placement.
- Spanner/ Activation key: straight instrument designed like screw holder which follows the contour of posterior part of the activation rod.
- Vulcanite bone cutting bur: for contouring the leading edge of the transport disc.

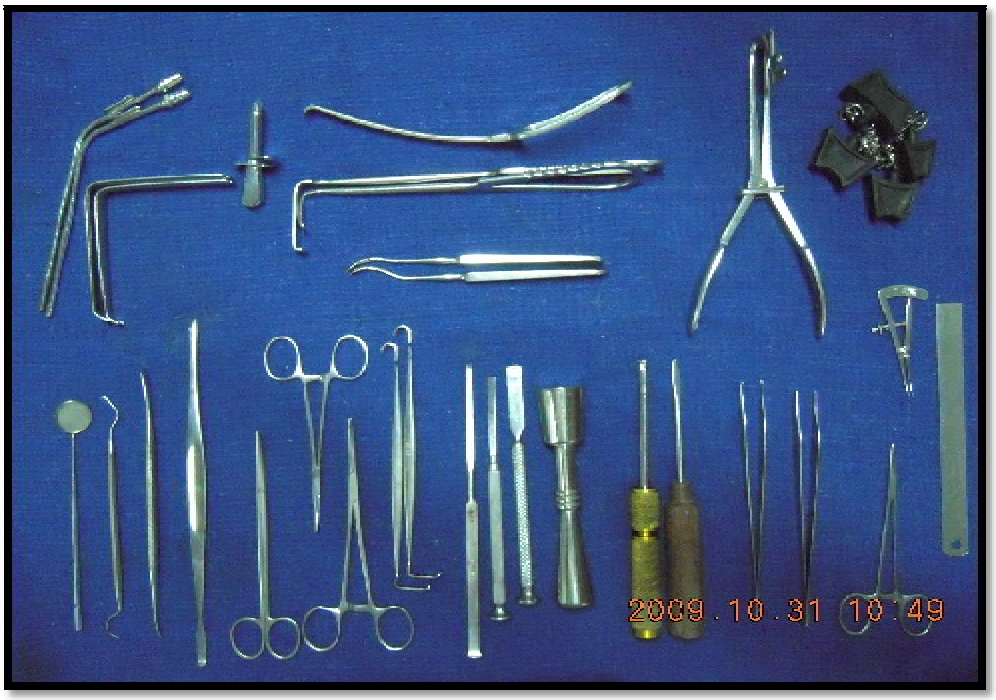
MEASUREMENT OF RAMUS HEIGHT

AFFECTED SIDE

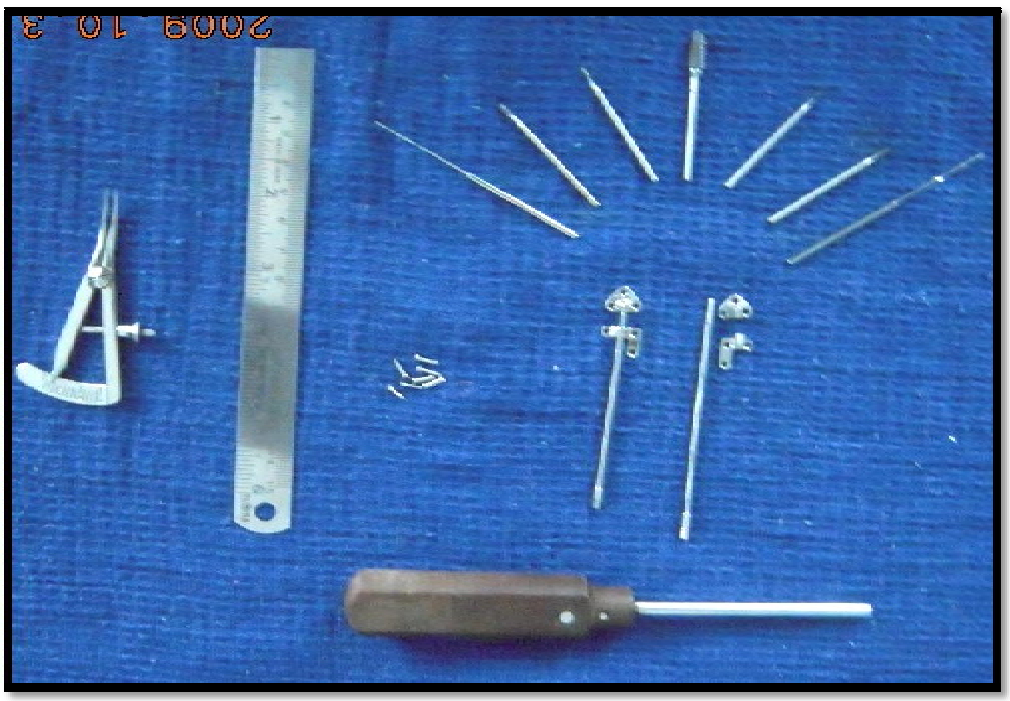


UNAFFECTED SIDE

ARMAMENTARIUM



DISTRACTION KIT



SURGICAL TECHNIQUE

SURGICAL TECHNIQUE

In our study,Naso endotracheal intubation was used for all patient.It was inserted either by blind nasal or fibreoptic technique depending upon the difficulty during intubation. Once the patient was intubated, scrubbing with betadine from forehead to neck region was done bilaterally and drapped to expose only the site of operation i.e., submandibular region .

Depending on diagnosis condylectomy was done via preauricular incision with alkyat bramley modification if needed, with interpositioning of myofascial temporalis flap.

Using marking ink skin incision was marked, about 2cm below angle and lower border of mandible approx 3-4cm in length parallel to skin creases. Layer wise dissection was done to expose the entire lateral ramus & angle region.

With the teeth in occlusion, an L shaped oeteotomy was designed from remaining posterior ramus and angle. The vertical limb parallels a vector that will bring the disk into the glenoid fosa. Following this osteotomy cut marked in lateral cortex using No. 701 bur.it was not completed . The leading edge of the disk was rounded to form a new condylar head using vulcanite bur.

Depending on shape & size of the defect , an appropriate internal distractor was choosen and placed along the planned vector. Attachment plates of the distractor was adapted & single screw of size 1.5 × 6 mm was inserted in plate. Then vector was checked. If it was corrected, then rest of the bicotical screws placed (3 in no.) in each plate.

The distractor was removed, and a full- thickness osteotomy was almost completed using fine osteotome, care should be taken to avoid injury to neurovascular bundles. After completing osteotomy , distractor was reattached. The distractor was opened to several turns to sure that transport disk moved freely. After confirming the successful separation of the segments device was kept in previous inactivated position.

The activation rod was brought out through a separate stab incision using 11 no. Blade in lower inconspicuous area, leaving sufficient area for suturing tissues without tension.

Layerwise closure of the surgical wound was done using 3-0 vicryl for pterygomasseteric sling, fascia and subcutaneous tissues and 3-0 prolene or silk for skin.

Pressure dressing was kept over the operated site.

Post operatively all patients received antibiotic and analgesics. All the patients were placed on soft diet & on active physiotherapy.

Distraction Protocol:

After a latency period of 7 days, distraction was done at the rate 1mm/day with a rhythm of 0.5mm twice daily. The activation was done till the desired length needed for correction . The device were left insitu for a consolidation period of 6-8 weeks till the evidence of bone formation is seen on the radiographs. After the consolidation phase,Under LA activation rod was removed leaving behind the attachment plates of device.

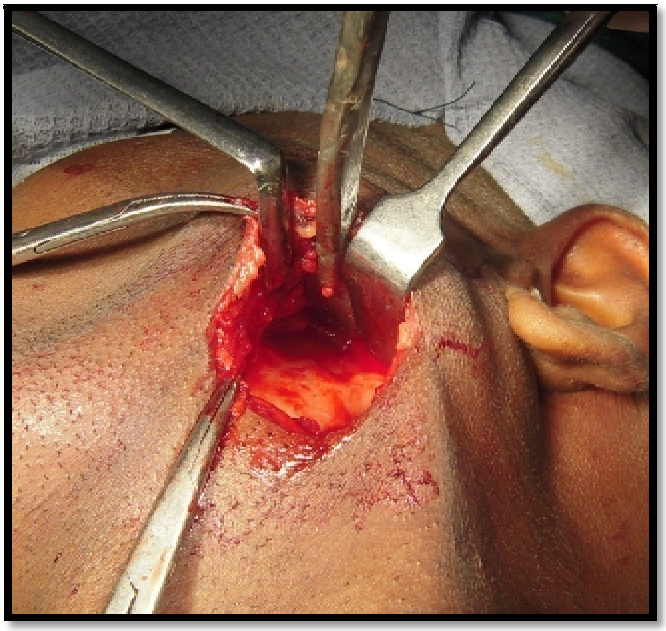
Follow up:

All the patients were asked to report to the out patient department for radiographic assessment once in a month to see the amount of bone formation. The follow up period ranges from minimum of 2 month to maximum of 5 months.

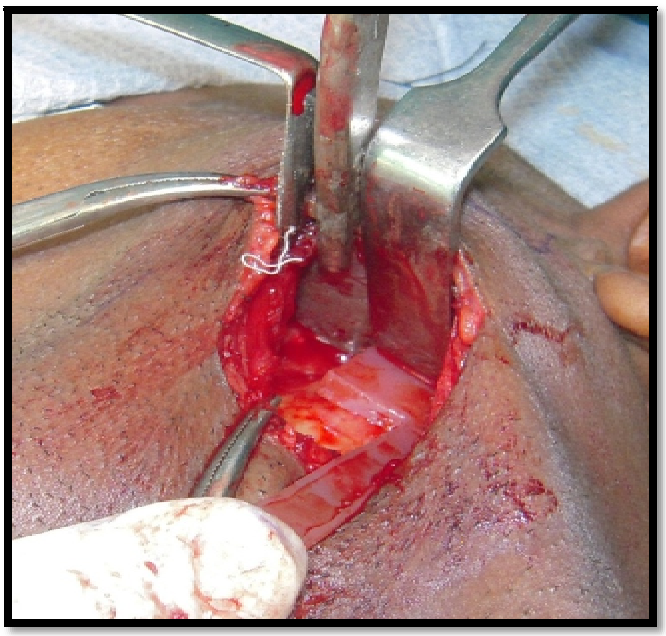
SURGICAL TECHNIQUE

Marking of the submandibular incision

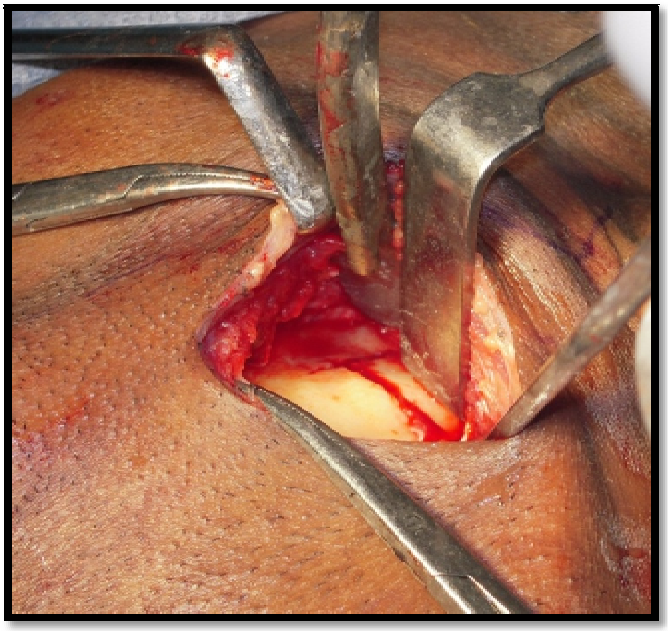
Placement of incision



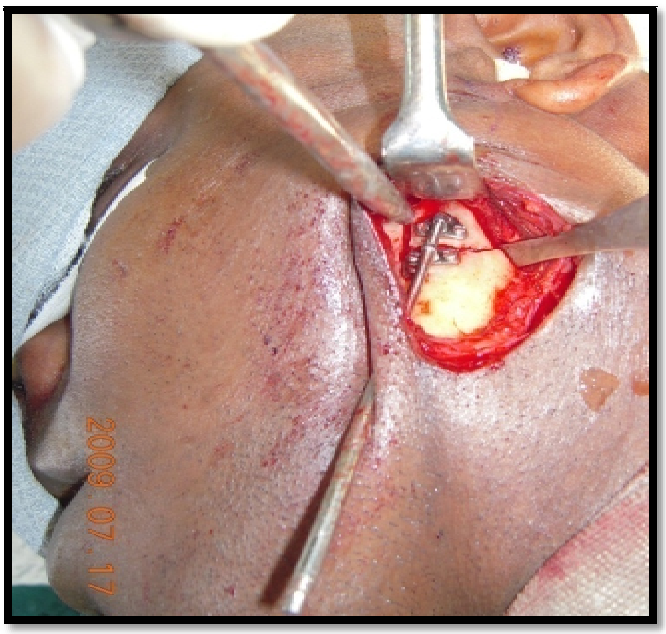
Exposure of lateral ramus and angle region after layer wise dissection.



Marking of the osteotomy cut using acrylic template over planned vector line.



Transport disk is created using L shaped osteotomy cut in remaining ramus region using 701 bur.



Devices placed and activation rod is brought out through separate stab incision.

Pterygomassetric sling and subcutaneous tissues sutured with 3-0 vicryl suture.

Subcuticular suturing done using 4-0 prolene suture for skin closure and tincture benzoin soaked cotton placed around

CASE REPORTS

CASE REPORT -1

NAME : Mr. Mohan Kumar

AGE/SEX : 36/M

CHIEF COMPLAINT : Complains of deviation of lower jaw on left side since 10 months.

PAST MEDICAL/SURGICAL HISTORY

Patient underwent for condylectomy for left side condylar hyperplasia 10 months back which was uneventful.

GENERAL EXAMINATION

Patient is moderately built & nourished.

LOCAL EXAMINATION

Extra oral examination:.

- Reduced vertical proportions of the mandible on left side compared to right
- Chin deviated to left side.

Intra Oral Examination

- Occlusion normal
- Mouth opening approx. 45mm
- Mild deviation of mandibular dental midline to the left side.
- Edge to edge anterior bite.

RADIOGRAPHIC FINDINGS

- OPG: Suggestive ramal deficiency on left side compared to right side.
- Lateral & frontal cephalogram:
  Suggestive of ramal deficiency on right side.
- 3D CT scan confirmed above mentioned findings.

CLINICAL PARAMETER OBTAINED

Vertical ramus deficiency = 0.8 cm

PROVISIONAL DIAGNOSIS

Secondary mandibular skeletal deformity on left side of the mandible.

TREATMENT PLAN

Reconstruction of the TMJ on left side using distraction osteogenesis.

PRE OP

POST OP

PRE OP

POST OP

PRE OP

POST OP

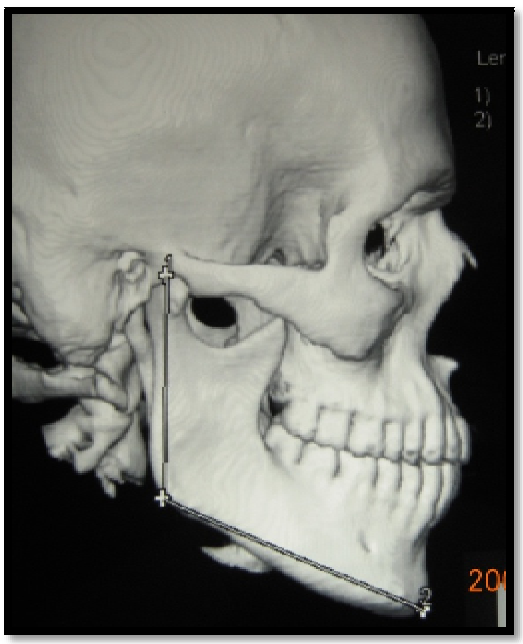
PRE OP

FRONTAL CEPH.

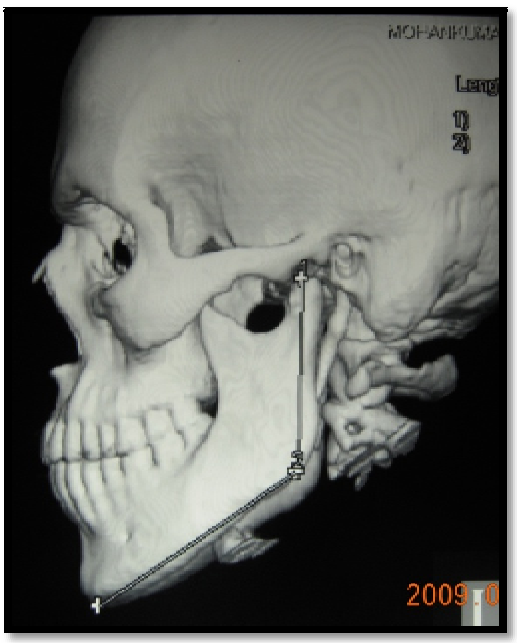
LATERAL CEPH.

3D CT SCAN

RIGHT LATERAL



LEFT LATERAL

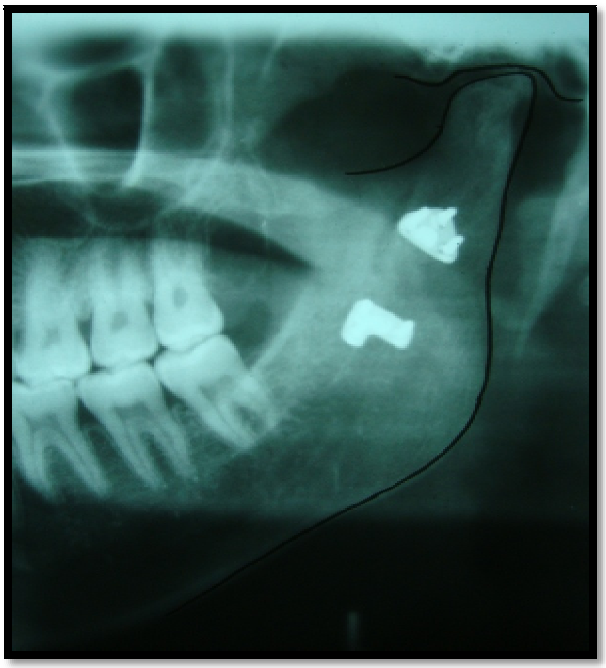


PRE OP

OPG (LEFT)

POST OP

OPG (LEFT)



CASE REPORT -2

NAME : Mr. Balachander

AGE/SEX : 14/M

CHIEF COMPLAINT : Complains of deviation of lower jaw on right side & also of facial disfigurement.

HISTORY OF PRESENT ILLNESS

Patient had inability to open mouth since childhood, following that he had developed facial asymmetry.

PAST MEDICAL/SURGICAL HISTORY

Patient underwent gap arthroplasty for right TMJ Ankylosis 2 years back, which was uneventful.

GENERAL EXAMINATION

Patient is poorly built & nourished.

LOCAL EXAMINATION

Extra oral examination:

- Facial asymmetry with fullness on the right side of face with flattening over left side of the mandibular body.
- Chin deviated to right side.
- Accentuation of the antegonial notch on right side.

- Intra Oral Examination
- Deep bite
- Mouth opening approx. 35mm
- Deviation of mandibular dental midline to the right side.
- Maxillary cant present.

RADIOGRAPHIC FINDINGS

- OPG: Suggestive ramal deficiency on right side compared to left side.
- Lateral & frontal cephalogram:
  Suggestive of ramal & body deficiency on right side.
- 3D CT scan confirmed above mentioned findings.

CLINICAL PARAMETER OBTAINED

Vertical ramus deficiency = 1.8 cm

PROVISIONAL DIAGNOSIS

Post ankylotic secondary mandibular skeletal deformity on right side.

TREATMENT PLAN

Reconstruction of the Ramus- condyle unit on right side using distraction osteogenesis.

PRE OP

POST OP

PRE OP

POST OP

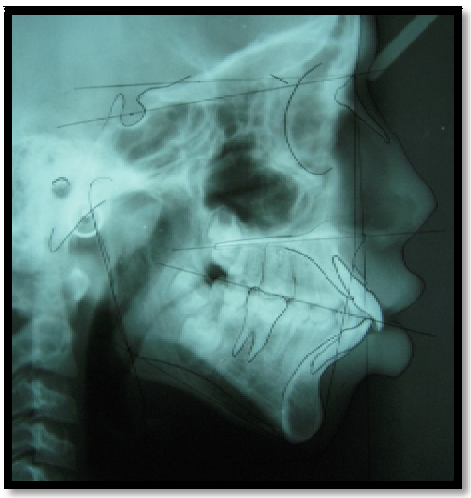
PRE OP

POST OP

PRE OP

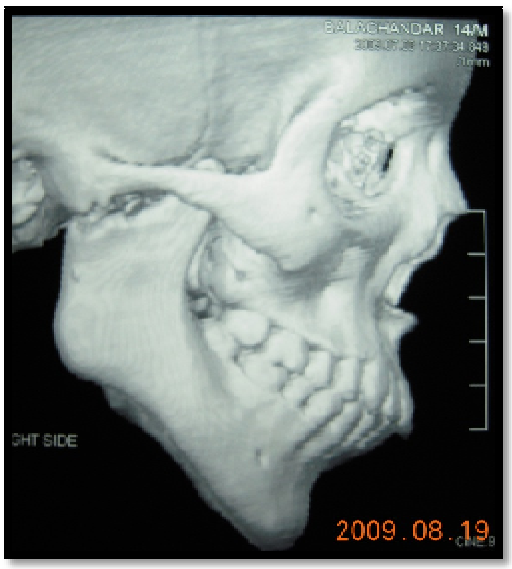
FRONTAL CEPH.

LATERAL CEPH.

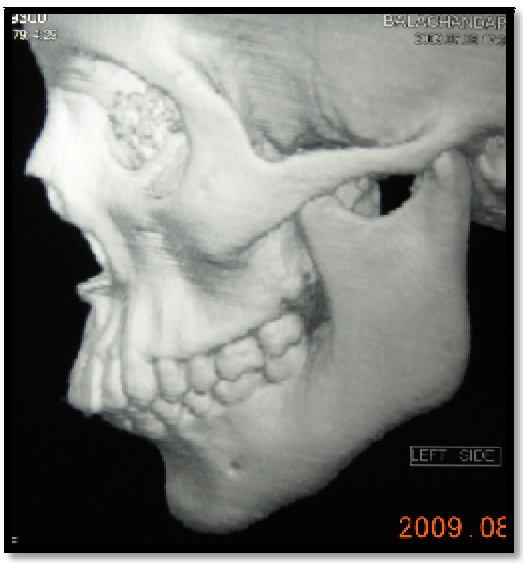


3-D CT SCAN

RIGHT LATERAL



LEFT LATERAL



PRE OP

OPG(RIGHT)

POST OP

OPG (RIGHT)

CASE – 3

NAME : Miss Preetha

AGE/SEX : 9/F

CHIEF COMPLAINT : Complaint of inability to open the mouth since childhood.

HISTORY OF PRESENT ILLNESS

Patient gave history of inability to open mouth since childhood following that she had developed facial asymmetry & also history of night snoring.

PAST MEDICAL HISTORY :

Patient had history of typhoid 1 month back for which she underwent for medication.

PAST SURGICAL HISTORY:

NRR

GENERAL EXAMINATION

Patient is poorly built & nourished.

LOCAL EXAMINATION

Extra oral examination:

- Mild TMJ movement palpable on both sides.
- Facial asymmetry with fullness on the right side of face with flattening over left side of the mandibular body.

- Chin deviated to right side.
- Accentuation of the antegonial notch on right side.
- Microgenia present.

Intra Oral Examination

- Deep bite
- Mouth opening is of approximately 6mm.
- Deviation of mandibular dental midline to the right side.

RADIOGRAPHIC FINDINGS

- OPG: Suggestive of bony ankylosis on right side TMJ region & also ramal deficiency on right side compared to left side.
- Lateral & frontal cephalogram:
  Suggestive of ramal & body deficiency on right side.
- 3D CT scan confirmed above mentioned findings.

CLINICAL PARAMETER OBTAINED

Vertical ramus deficiency = 1.6cm

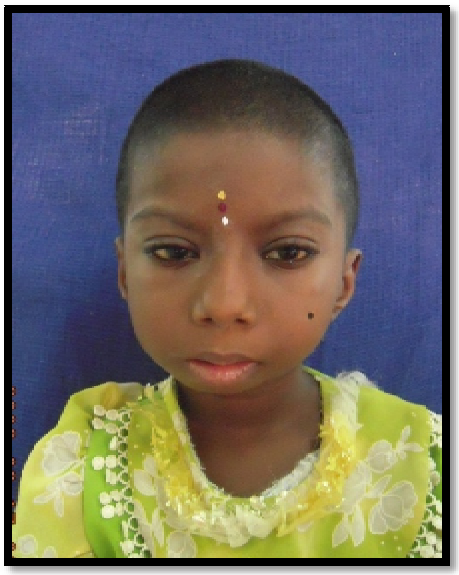
PROVISIONAL DIAGNOSIS

Unilateral (right) TMJ Ankylosis

TREATMENT PLAN

Simultaneous Interpositional arthroplasty using temporalis myofascial flap for right side followed by reconstruction of TMJ using Distraction ostiogenesis.

PRE OP



POST OP

PRE OP

POST OP

PREOP

POST OP

PREOP

POST OP

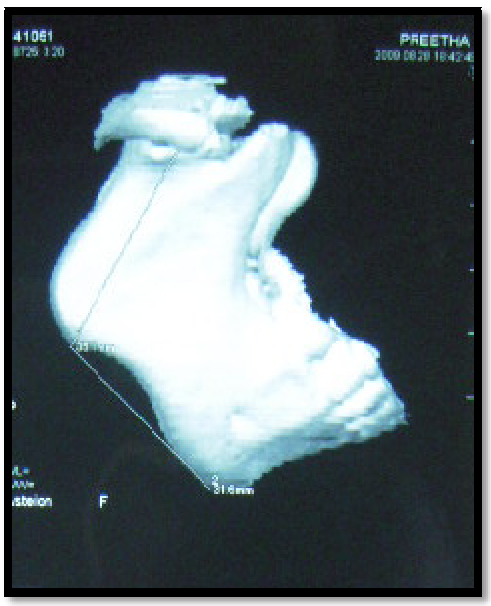
PRE OP

FRONTAL CEPH.

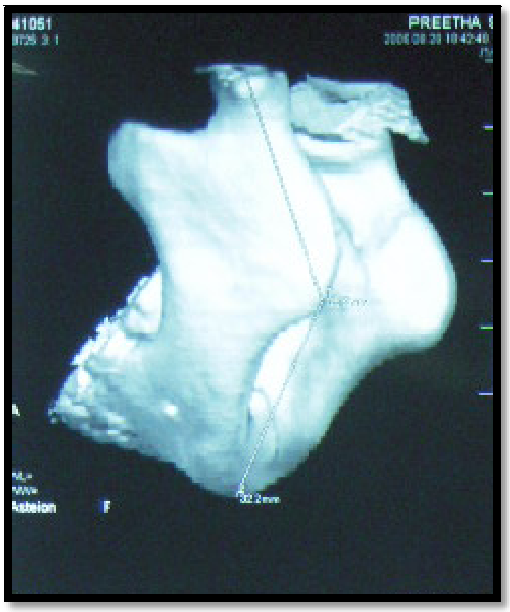
LATERAL CEPH.

3D CT SCAN

RIGHT LATERAL

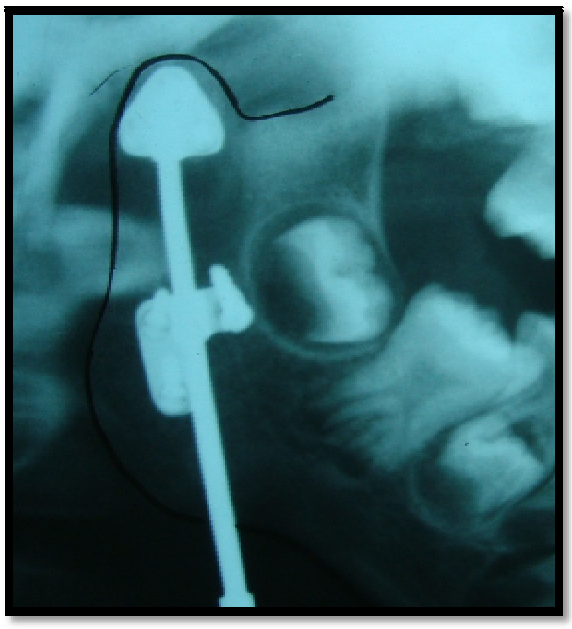


LEFT LATERAL



PRE OP

POST OP



CASE – 4

NAME : Mr. Vijay

AGE/SEX : 16/M

CHIEF COMPLAINT : Complaint of inability to open the mouth last 4 years & also of facial asymmetry.

HISTORY OF PRESENT ILLNESS

Patient gave history of inability to open mouth last 4 years following trauma.

PAST MEDICAL/SURGICAL HISTORY

NRR

GENERAL EXAMINATION

Patient is moderately built & nourished.

LOCAL EXAMINATION

Extra oral examination:

- Mild TMJ movement palpable on both sides.
- Facial asymmetry with fullness on the left side of face with flattening over right side of the mandibular body.
- Chin deviated to left side.
- Accentuation of the antegonial notch on left side.

Intra Oral Examination

- Deep bite
- Mouth opening is of approximately 16mm.
- Mild deviation of mandibular dental midline to the left side.

RADIOGRAPHIC FINDINGS

- OPG: Suggestive of bony ankylosis on left side TMJ region & also ramal deficiency on left side compared to right side.
- Lateral & frontal cephalogram:
  Suggestive of ramal & body deficiency on left side.
- 3D CT scan confirmed above mentioned findings.

Clinical parameter obtained

Vertical ramus deficiency = 1.2cm

PROVISIONAL DIAGNOSIS

Post traumatic unilateral TMJ ankylosis on left side.

TREATMENT PLAN

Simultaneous Interpositional arthroplasty using temporalis myofascial flap for left side followed by reconstruction of TMJ using Distraction osteogenesis.

PRE OP

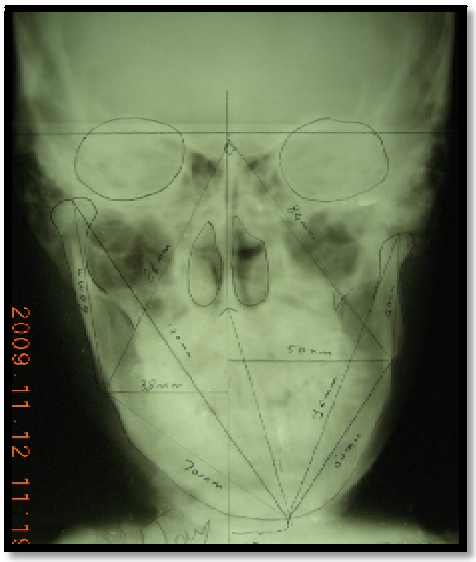
POST OP

PRE OP

POST OP

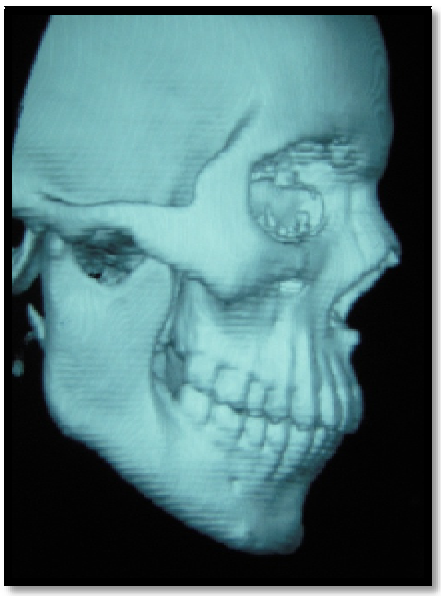
PRE OP

FRONTAL CEPH.



3-D CT SCAN

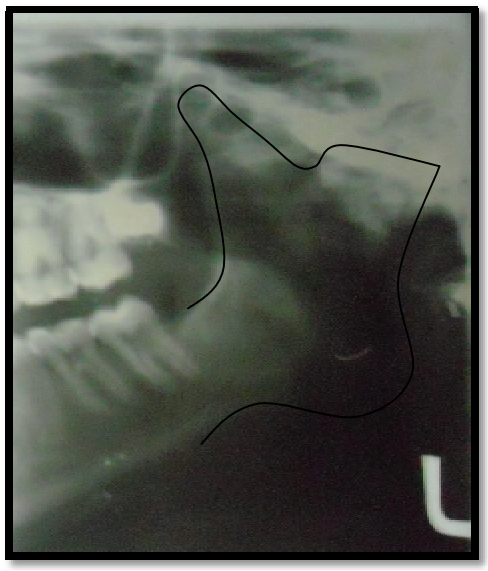
RIGHT LATERAL



LEFT LATERAL

PRE OP

OPG (LEFT)



POST OP

OPG(LEFT)

OBSERVATIONS & RESULTS

OBSERVATIONS & RESULTS

In our study, we used an indigenously designed internal unilateral distraction device for reconstruction of the Ramus- Condyle unit & It showed good results.

In this study, four patients were included. One patient had condylar hyperplasia for whom condylectomy was done earlier, other was treated TMJ ankylotic case & rest of two were of unilateral TMJ ankylosis cases . these two cases underwent for simultaneous Interpositional arthroplasty followed by Distraction Osteogenesis.

Radiographs were taken periodically to assess these patients. Radiographs showed evidence of bone formation taken at the end of consolidation period.

In our study , three of our patients showed good results except one where we encountered device failure

Complications like injury to neurovascular bundles & marginal mandibular nerve, infections were not encountered in our study.

All the patients are followed periodically of evaluated for bone formation.The follow up period in this study ranges from a minimum of 2 months to maximum of 5 months.

Occlusion:

Preoperatively all three patients had stable occlusion. Amongst them two patients had midline shift and maxillary cant. At the end of distraction phase we encounterd with ipsilateral open bite in 2 patients that was corrected itself during consolidation period due to supraeruption of teeth. In one patientthe dental midline was automatically corrected following distraction.

Mouth opening:

2 out of 3 patients had maximum interincisal mouth opening greater or equal to their preoperative level , whereas one patient had maximum interincisal slightly below the mouth opening which we achieved after the release of TMJ.

Deviation of chin:

Preoperatively, chin deviation was present while opening the mouth . No chin deviation was observed postoperatively in all patients.

Facial Esthetics:

At the end of desired lengthening of all the three patients, they showd satisfactory facial esthetics. We also observed better soft tissue profile.

Pain control:

None of our patients had chronic pain . Good pain control was acchived in all cases.

The results are summarized in the tabular column:-

Patient Name,Age & Sex	***Diagnosis***	***Treatment planned***	***Pre operative Ramus lengthening required (cm)***	***Post Operative ramus lengthening achieved (cm)***	***Deviation of chin***		***Mouth opening***	***Occlusion***	***Post operative Facial esthetics***
					Pre operatively	***Post operatively***			
Mohankumar 36/M	Treated case of left condylar hyperplasia	Distraction osteogenesis	0.8 cm	0.8 cm	Towards left side	No deviation	Remained same	Normal	Good
Balachander, 14/M	Treated case of unilateral right TMJ ankylosis	Distraction osteogenesis	1.8 cm	1.6 cm	Towards right side	No deviation	Improved	Dental mid line shift corrected	Good
Preetha 9/F	Unilateral right TMJ Ankylosis	Interpositional arthroplasty followed by Distraction osteogenesis	1.6 cm	1.6 cm	---	---	Preop.- 5mm After TMJ release – 28mm Postop. After consolidation period - 20mm	Normal	satisfactory
Vijay 16/M	Post traumatic Unilateral left TMJ Ankylosis	Interpositional arthroplasty followed by Distraction osteogenesis	1.4cm	Distraction not done because of device failure	---	---	Preoperatively 16mm Postoperatively 36mm	----	----

DISCUSSION

DISCUSSION

TMJ plays imprtant role in establishing & maintaining proper form & function within the stomatognathic system[4].

TMJ is essential to the functions of mastication, speech, airway support & deglutition in both children & adulthood[4].

Goals for any TMJ reconstruction modality are :-

a) Improvement of mandibular functions & form.
b) Reduction of further suffering & disability.
c) Containment of excessive treatment & cost.
d) Prevention of further morbidity.

Various materials like vascularised & nonvascularised autogenous bone & alloplasts have been used for reconstruction of TMJ from last many decades, but each material has their own merits & demerits.

Nonvascularised autogenous grafts like CCG, SCG, metatarsal , illiac crest & fibula head[12,13,,23,35,40,73] have been reported earlier for reconstruction of TMJ.

Autogenous tissues have advantages[12,36,53] of being biologically acceptable & possesing growth & remodelling potential.

Complications[45,61] associated with use of autogenous grafts are:-

- Donor site morbidity

- Inceased surgical time
- Occlusal unstability due to resorption & excessive growth
- Fractures
- Recurrence of ankylosis

TMJ reconstruction has also been performed using vascularised rib, fibular forearm flap & metatarsal flap[6,10,16,21,70]. However , none of the reports provided the long term followup information.

Several alloplastic prosthesis like christensen, kent-vitek, AO/ASIF, delrin & custom made tech medica[33,45,61,67,71] have been introduced to overcome the demerits of autogenous materials like donor site morbidity but these prosthesis are associated with following complications[4,61,72]:-

- Prosthesis displacement or fractures
- Foreign body reactions to polymerise & metallic debris.
- Heterogenous bone formation which causes ankylosis of the prosthesis.
- Lack of growth potential precluding the use of these joint repacement system in young children.
- May cause bony erosion in the area of the glenoid fossa.

Recently Transport distraction osteogenesis has been proposed for the reconstruction of Ramus condyle unit[29,66].

Distraction Osteogensis is defined as "the regeneration of bone between vascularised bone surfaces that are separated by gradual distraction" [30]. It offers several advantages[4,28,63] over traditional surgical techniques for reconstruction of TMJ. They are,

Ø Less invasive and no donor site morbidity.

- Ø Rigid distraction device allows for immediate postoperative physical therapy, which allows formation of a pseudoarthrosis & prevent ankylosis.
- Ø Risk of bone graft necrosis & resorption is greatly reduced compared to nonvascularised free bone grafts(because transport bone retains its internal muscle & periosteal blood supply).
- Ø No foreign body reactions.
- Ø Proportional & harmonic modification of the muscles and surrounding soft tissues is obtained.
- Ø The direction and amount of bony lengthening can be controlled.
- Ø Forces produced, during callus distraction are very similar to physiologic forces and favour the correct development of the mandible.
- Ø It shortens the admission and operation time.
- Ø It reduces possibility of relapse with no bone grafting.

Distraction osteogenesis can be carried out by internal [7] and external devices. In our study we have used Internal Distractor.

Principles and biomechanics involved in Distraction osteogenesis:-

Distraction vector planning[30,62]:-

Distraction vector is defined as "the desired direction that the distal segment must move during lengthening" [30].

Factor that affect[62] the vector of distraction include,

1. Osteotomy design and location.
2. Distraction device orientation
3. Occlusal interferences.

a) Osteotomy design and location:

The ostetomy design is dictated by the anatomic region to be lengthened .

This osteotomy cut should be placed in a location that will allow for optimal bone generation as well as for proper device placement.

In our study L shaped osteotomy cut[4,29,66] has been designed on the lateral aspect of ramus of the mandible extending from sigmoid notch . Vector for vertical osteotomy cut was designed in such a way that transport disc should go towards the glenoid fossa. Horizontal cut was designed parallel to lower border of the mandible.

b) *Distraction Device Orientation:*

Although, osteotomy design and location may affect the muscle tension exerted on the proximal and distal segments, distraction device orientation in the primary factor that influences the vector of distraction[62].

In order to minimize adverse biomechanical effects, devices should be placed parallel to the desired vector of distraction.

c) *Occlusal interferences:*

May also alter the planned distraction vector[62].

Osteotomy:-

Defined "As a low energy ostetomy of the cortex preserving the local blood supply to both the periosteum and medullary canal" [30,62] .

We followed the technique advised by Joseph G McCarthy (1992)[30] and Molina (1995)[62], to create an atraumatic bone discontinuity.

First, the buccal corticotomy was made, through buccal cut. Then using the fine osteotome the lingual cortex was fractured.Every care taken to preserve the integrity of neurovascular bundles[4,29] .

Discontinuity of skeletal segment triggers an evolutionary process of bone repair known as 'fracture healing' which involves recruitment of osteoprogenitor cells, followed by cellular modulation or osteoinduction and establishment of an environmental template for osteoconduction[30] .

Latency period:-

Latency is "the time following the ostetomy when initial fracture healing bridges the cut bone surface prior to initiating distraction" [30] .

To optimize the response of osteogenic tissue to distraction, a latency period has been suggested for early callus formation (mesenchymal tissue reaction) [30.62].

Different latency periods has been suggested, ranging from 5-21 days have been reported in clinical studies and animal experiments.

A latency period of 7 days[2,43,48] was given for all the patients in our study. On the eighth post operative day we started distraction.

Rate of Distraction:-

Rate is “the number of millimetres per day at which the bone surface are stretched”.

Illizarov [25] principles stressed the importance of one mm of activation rate per day for optimal results.

Quality and quantity of newly formed bone increases when distraction is performed continuously at a rate of 1mm/day[30] .

In our study we did an advancement of 1mm per day according to the principles of illizarov[25].

Rhythm of Distraction:-

“It is the number of distractions per day usually in equally divided increments to the total rate”[30] .

The force of distraction should ideally be applied as a continous rhythm, yet dividing the bone advancement into twice daily or four times daily application is more practical for the patient[30].

McCarthy [43](1992) suggested rhythm of distraction from two (0.5mm) or four (0.25mm) times a day.

We followed 0.5mm twice daily rhythm for distraction.

Consolidation:-

A consolidation period of 6-8 weeks following the desired advancement by distraction is adviced[43,48,62] . The device to be removed after radiographic evidence of bone formation. A periodic follow up to assess the changes following distraction is mandatory.

In this study, we used detachable internal distractor, so only activation rod was removed after the radiographic evidence of bone formation was seen that is approximately after 6-8 weeks. All the patients were kept under periodic observation.

As concluded by various researchers[43,48,62] in their study we do find expansion of the soft tissues over affected side following DO with improved facial esthetics.

Complications:-

Complications encountered during craniofacial distraction osteogenesis can be divided into three groups.

a) Intraoperative complication
b) Intradistraction complication
c) Post distraction bone healing complication

a) *Intra operative complications*[43,48] *that can be encountered are,*

- Bleeding problems
- Neurosensory deficits
- Less than optimum bone split as the corticotomy is converted to an osteotomy.

- Device associated complications like placement/orientation of the device.
- Completeness of the osteotomy.

b) *Intra distraction complication*[4,43,48,62] *are associated with the distraction &consolidation periods including:*

- Infections
- Device loosening & dislodgement
- Device failure
- Activation rod tract formation with subsequent scarring.
- Inappropriate distraction vector.
- Premature consolidation.
- Trismus

c) *Post distraction bone healing*[30] *complication of distraction procedure:*

- Premature consolidation - incomplete corticotomy.
- Delayed consolidation.
- Late bowing of the regenerate.
- Complete stress fracture of the regenerate after fixator removal.
- Incomplete lengthening.

CONCLUSION

CONCLUSION

Reconstruction of the TMJ has proved to be a challenging & complicated endeaver.

Distraction osteogenesis has revolutionized surgical reconstruction with regards to head & neck region.

Distraction osteogenesis allows for attainment of many of the goals needed for sucessful TMJ reconstruction.

Distraction osteogenesis has proved to be safe & effective due to its unique advantages like low risk , decreased morbidity , simple manipulation , high curative rate , less relapse with stable results.

Skeletal distractrion proceeds parallel to expansion of soft tissues, thereby accheiving better aesthetic results. This proves it to be superior to other reconstructive procedures.

Distraction osteogenesis is being a sensitive procedure, requires careful planning & execution following the vector principle.

Patient compliance during the entire treatment period is essential & thus careful patient selection & adequate motivation is of utmost importance.

Although number of cases & period of followup is minimal in our study , this technique of using Indigeniously designed Internal distraction device for reconstruction of TMJ has shown good results among the study group.

We conclude by saying that Distraction osteogenesis can be considered as an effective treatment of choice for reconstruction of TMJ. However to know the long term effects of distraction, periodic followup is essential.

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ANNEXURE

INFORMED CONSENT

Department of Oral & Maxillofacial Surgery

Tamil Nadu Govt. Dental College & Hospital, Chennai-3.

You have the right to be informed about your condition & the recommended treatment plan so that you make an educated decision as to whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to alarm you, but is rather an effort to provide information so that you may give or withhold your consent.

Title of the study:

Reconstruction of the Temporomandibular Join using Distraction Osteogenesis.

Name: Age/Sex:

Date of Birth:

Responsible Health professional:

Purpose & Background:

Under the supervision of …….. Professor of Department of Oral & Maxillofacial surgery at Tamil Nadu Government

Dental College & Hospital Chennai, a postgraduate student is conducting this study. The purpose of this study is to evaluate the use of transport distraction osteogenesis in the reconstruction of Ramus-Condyle unit of the Temporomanddibular joint by using an indigeniously designed internal distraction device.

Please initial each paragraph after reading. If you have any questions, please ask your doctor **BEFORE** initializing.

1. My condition has seen explained to me as a lower jaw deformity secondary to condylar injuries,TMJ ankylosis, degenerative disease of the joints.

2. The procedure(s) necessary to treat the condition have been explained to me & I understand the nature of the treatment to be,

    i) The surgical procedure that involves cuts, that are made in the lower jaw.

    ii) The approach to expose the lower jaw is external below the lower border of jaw from the skin.

iii) The distraction device will be placed internally and activation rod brought out through skin below the lower jaw.

iv) Duration of treatment of about 3-4 months has been explained to me as, time required till completion of the treatment.

v) Post operatively social inconvenience due to device fixation has been explained.

vi) The surgery is performed under general anaesthesia where the anaesthesia time may range from 4-5 hrs.

vii) Any extra procedure which may become necessary during the surgical procedure are:

1. Blood transfusion
2. Urinary catheterization
3. Ryle's tube insertion

viii) Video of the surgical procedure shall be taken. Video shall be used only by the researcher and stored later on.

Statement of Health Professional

I have explained the procedure to the patient in particular I have explained the intended benefits.

The surgery is done to give good patient function and esthetic post operatively.

Gives psychological comfort as this procedure corrects secondary deformity.

Risks:

1. Risks of infection.

2. Temporary loss of sensation with lower jaw teeth.

3. Relapses in case of device failure.

Costs:

There will be no expenditure to me as a result of taking part in the study.

Questions:

I have spoke with ……. about this study and have had my questions answered.

If I have any further question about the study. I can contact or write to them to the Department of oral & maxillofacial surgery, Tamil Nadu Government Dental College & Hospital, Chennai-3.

Consent:

I have been given a copy of this consent form to keep.

Confidentiality:

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded & will not be associated with any published results. Your code number of identity will be there in the thesis dissertation of the investigator all tapes and photographs will be given codes and stored separately from any names or other direct identification of participants only research person will have access to the files & the videos.

Participation in the study is voluntary. I am free to declaim to participate in the study or I may withdraw my participation at any point without penalty.

I agree to take part in this study as a research participant. By my signature I affirm that I am at least 18 year old & I have received a copy of this consent form.

I hereby authorize Dr…… and staff to perform the following procedures ..... under General Anaesthesia.

Participant name *Date* *Participant signature*